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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,059	02/27/2002	Jose Gutierrez-Rocca	SD-20003	1436
7590 Kos Pharmaceuticals, Inc 1 Cedar Brook Drive Cranbury, NJ 08512			EXAMINER WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/086,059	Applicant(s) GUTIERREZ-ROCCA ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 9-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 9-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Detailed Action

Response to Amendment

Specification

The amendment filed 1/27/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The applicants have proposed the replacing of the second full paragraph on page 6 of the specification with an amended paragraph wherein the terms "methyl, ethyl...Methocel A, Methocel K...the Ethocels, for example Ethocel P20" are removed. The applicants provide no basis or reasoning why such a change in the specification is to be made. The original filing included the terms and the original claim set included the terms. There are no arguments presented to support the amendment of the specification to exclude the terms and no indication in the specification as to why the terms would be excluded in any particular embodiment.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1, 3 13, 15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner respectfully points out that the applicant's have pointed to page 2 lines 14-16 and page 6 lines 7-9 as supporting the proposed claim amendments and insertion of new claim 17 (see remarks page 6). In the remarks on page 6, the applicants fail to disclose if the section of page 6 referred to in the specification as one of the basis for support of the amendments is to be the proposed amended specification or the original specification. Regardless of this, the examiner can find no support for the insertion of the proposed changes in the claims in the sections pointed out by the applicants. In particular the insertion of the language "mixture of at least one" in claim 1 is not detailed in either section, nor can the examiner find any basis in the specification as a whole. The applicants have canceled the term "mixture" and inserted the term "construct". The examiner cannot find any support for the interchangeability of this terms nor any basis for the insertion of the term construct for mixture in the context of the claims based upon the sections pointed out by the applicant's. Page 2 lines 3-6 of the specification states: "A suitable carrier construct comprises a mixture of polymers. The polymer mixture comprises..." this seems to define a carrier construct as a mixture of polymers but does not support the changing the term mixture with construct as proposed. Indeed the examiner cannot find the term polymer construct in the sections pointed out by the applicant. Further the applicant has added "and wherein said second component comprises from about 2 to about 60 weight percent of the total formulation" to claim 1. On page 2, lines 14-16 of the specification it reads: "The first component of the polymer mixture further comprising an amount from

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about 20 weight percent to about 90 weight percent of the total weight of the formulation or construct and the second component further comprising an amount from about 2 weight percent to about 60 weight percent of the total weight of the formulation or construct...". The section utilized for support clearly indicates that the ranges inserted by the applicant were originally drawn to the weight percent of the total formulation or construct. There is no basis for exclusion of the language as proposed in the claim and as the specification is originally drawn to 20-90 and not 45-90 there is no support for the exclusion of the range 20-44 in the specification section pointed to as providing support. Claim 3 has been amended to change it from a Markush claim to read "wherein said at least one cellulose ether polymer has..." as noted above the insertion of the language "at least one" has no support and therefore is new matter. Thus amended claim 3 is also drawn to new matter as including the same language. Claims 13, 15 and 17 are considered new matter for the same reasons as above.

As such the amendment of 1/27/2006 is not entered.

For the reasons stated above and for reasons of record the 102(e) and 103(a) rejections of record are maintained. The rejections are detailed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 9-11, and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Corbo et al. (US Patent No. 6551617).

Corbo et al. teach, in col. 2 line 40 to col. 3 line 25, a coating composition comprising polyvinyl acetate, dimethylaminoethyl methacrylate, neutral methacrylic acid, and a medicament. The polyvinyl acetate used in the formulation can be a blend such as KOLLIDON SR (a polyvinyl acetate/polyvinylpyrrolidone blend; ~8:2) and is present in the composition in ranges from 3-97% by weight. Corbo et al. teach, in col. 4 lines 55-65, that the compositions can contain ethyl cellulose as an additive and is present in amounts from 10-30% by weight. Corbo et al. teach, in col. 5 lines 15-40, that the coated medicament can be in the form of powders, tablets, liquid preparations, lozenges, wafers, chewing gums and that the medicament present can include acetaminophen, aspirin, ibuprofen, rantidine, catopril etc.. anticipating the "...sustained/prolonged release pharmaceutical formulation...." of claim 1 and the "...formulation...wherein said water-soluble medicament is selected from..." of claims 4 and 10.

Corbo et al. teach, in col. 5 lines 37-56, that the coated medicament can be prepared by coating granules or crystals of a drug with the coating composition in a fluid bed chamber combining the coated granules or crystals with ingredients commonly

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used for making tablets, then compressing the mixture in tablet form anticipating the "...process for the preparation of the sustained/prolonged release pharmaceutical..." of claim 9 and the "...formulation...which comprises a modulated release pharmaceutical construct..." of claim 11, the "...process for preparing the sustained/prolonged release pharmaceutical formulation..." of claim 13, the "...process...wherein said tableting is conducted under direct pressure..." of claim 14, the "...process...wherein said polymer and drug are blended by means of wet granulation followed by dry blending..." of claim 15, and the "...process....wherein all material are wetted prior to said blending and dried and milled after blending..." of claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbo et al. (US Patent No. 6551617).

Corbo et al. teach, in col. 4 lines 55-65, that the compositions can contain ethyl cellulose as an additive and that the ethyl cellulose is present in amounts from 10-30% by weight.

Corbo et al. does not teach the particular cellulose ethers of claim 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the commercially available cellulose ethers presented in claim 3 could be used in the coating composition of Corbo et al. One would have been motivated to use any of the listed commercially available cellulose ethers as they are well known, have stable and defined properties, and are commonly used in pharmaceutical formulations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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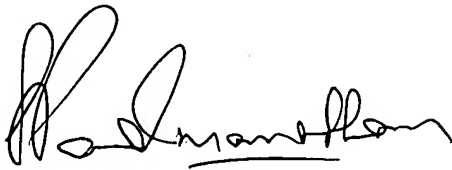
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



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